THAT WHICH IS CLAIMED IS:

1.   A method for preparing an injectable formulation of interferon-beta (IFN-β) comprising:

a)   preparing a first solution comprising IFN-β, isolating a pool of purified IFN-β from this solution, and precipitating said IFN-β from this pool using an alcohol to form a precipitate;

b)   dissolving said precipitate in guanidine hydrochloride (HCl) to form a second solution comprising resolubilized denatured IFN-β and guanidine HCl;

c)   diluting said second solution into a first buffer to obtain a third solution comprising resolubilized renatured IFN-beta and residual guanidine HCl; and

d)   removing residual guanidine HCl from said third solution by diafiltration or dialysis of said third solution into a second buffer that is pharmaceutically acceptable, whereby said injectable formulation of IFN-β is prepared.

2.   The method of claim 1, wherein said second buffer contains arginine or sodium chloride.

3.   The method of claim 1, wherein said first buffer has a pH of about 5.0 to about 8.0, and wherein said residual guanidine HCl is present in said third solution at a concentration of 1.6 M or less.

4.   The method of claim 1, wherein said IFN-β has the amino acid sequence set forth in SEQ ID NO:1 or SEQ ID NO:2.

5.   The method of claim 1, wherein said IFN-β is glycosylated or unglycosylated.

6.   The method of claim 1, wherein said IFN-β is recombinantly produced.

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7.   The method of claim 1, wherein said IFN-β has at least 80% amino acid sequence identity with the amino acid sequence set forth in SEQ ID NO:1 as calculated using the ALIGN program with a PAM 120 weight residue table, a gap length penalty of 12, and a gap penalty of 4.

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8.   A method for preparing an injectable formulation of interferon-beta (IFN-β), said method comprising denaturation of IFN-β with guanidine hydrochloride (HCl) followed by renaturation of the IFN-β via dilution into a first buffer to obtain a renatured IFN-β solution comprising residual guanidine HCl, and removing said residual guanidine

10   HCl from said renatured IFN-β solution by diafiltration or dialysis of said renatured IFN-β solution into a second buffer that is pharmaceutically acceptable, whereby said injectable formulation of IFN-β is prepared.

9.   The method of claim 8, wherein said first buffer has a pH of about 3.0 to

15   about 5.0, and wherein said residual guanidine HCl is present in said renatured IFN-β solution at a concentration of 1.6 M or less.

10.   The method of claim 9, wherein said first buffer has a pH of about 3.0 to about 4.0, and wherein said residual guanidine HCl is present in said renatured IFN-β

20   solution at a concentration of 0.2 M or less.

11.   The method of claim 10, wherein said first buffer has a pH of about 3.0, and wherein said residual guanidine HCl is present in said renatured IFN-β solution at a concentration of 0.1 M or less.

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12.   The method of claim 8, wherein said IFN-β has the amino acid sequence set forth in SEQ ID NO:1 or SEQ ID NO:2.

13.   The method of claim 8, wherein said IFN-β is glycosylated or

30   unglycosylated.

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14.   The method of claim 8, wherein said IFN-β is recombinantly produced.

15.   The method of claim 8, wherein said IFN-β has at least 80% amino acid sequence identity with the amino acid sequence set forth in SEQ ID NO:1 as calculated using the ALIGN program with a PAM 120 weight residue table, a gap length penalty of 12, and a gap penalty of 4.

16.   A method for preparing a composition comprising substantially monomeric interferon-beta (IFN-β), said method comprising:

    a)   preparing a precipitate of substantially purified IFN-β;

    b)   dissolving said precipitate in guanidine hydrochloride (HCl) to obtain a first solution comprising resolubilized denatured IFN-β; and

    c)   renaturing said IFN-β by dilution of said first solution with a buffer solution.

17.   The method of claim 16, wherein said buffer solution has a pH of about 5.0 to about 8.0.

18.   The method of claim 16, wherein said IFN-β has the amino acid sequence set forth in SEQ ID NO:1 or SEQ ID NO:2.

19.   The method of claim 16, wherein said IFN-β is glycosylated or unglycosylated.

20.   The method of claim 16, wherein said IFN-β is recombinantly produced.

21.   The method of claim 16, wherein said IFN-β has at least 80% amino acid sequence identity with the amino acid sequence set forth in SEQ ID NO:1 as calculated using the ALIGN program with a PAM 120 weight residue table, a gap length penalty of 12, and a gap penalty of 4.

22.   A method for preparing an injectable formulation of interferon-beta (IFN-β), said method comprising:

a)   obtaining a sample comprising substantially purified IFN-β;

b)   mixing said sample with guanidine hydrochloride (HCl) to obtain a first solution comprising solubilized denatured IFN-β;

c)   diluting said first solution into a first buffer to obtain a second solution comprising solubilized renatured IFN-beta and residual guanidine HCl; and

d)   removing residual guanidine HCl from said second solution by diafiltration or dialysis of said second solution into a second buffer that is pharmaceutically acceptable, whereby said injectable formulation of IFN-β is prepared.

23.   The method of claim 22, wherein said first buffer has a pH of about 3.0 to about 5.0, and wherein said residual guanidine HCl is present in said second solution at a concentration of 1.6 M or less.

24.   The method of claim 23, wherein said first buffer has a pH of about 3.0 to about 4.0, and wherein said residual guanidine HCl is present in said second solution at a concentration of 0.2 M or less.

25.   The method of claim 24, wherein said first buffer has a pH of about 3.0, and wherein said residual guanidine HCl is present in said renatured IFN-β solution at a concentration of 0.1 M or less.

26.   The method of claim 22, wherein said IFN-β has the amino acid sequence set forth in SEQ ID NO:1 or SEQ ID NO:2.

27.   The method of claim 22, wherein said IFN-β is glycosylated or unglycosylated.

28.   The method of claim 22, wherein said IFN-β is recombinantly produced.

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29.   The method of claim 22, wherein said IFN-β has at least 80% amino acid sequence identity with the amino acid sequence set forth in SEQ ID NO:1 as calculated using the ALIGN program with a PAM 120 weight residue table, a gap length penalty of 12, and a gap penalty of 4.

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30.   A method for preparing a composition comprising substantially monomeric interferon-beta (IFN-β), said method comprising:

a)   preparing a sample comprising substantially purified IFN-β;

b)   mixing said sample with guanidine hydrochloride (HCl) to obtain a

10   first solution comprising solubilized denatured IFN-β; and

c)   renaturing said IFN-β by dilution of said first solution with a buffer solution.

31.   The method of claim 30, wherein said buffer solution has a pH of about

15   3.0 to about 5.0.

32.   The method of claim 30, wherein said IFN-β has the amino acid sequence set forth in SEQ ID NO:1 or SEQ ID NO:2.

20   33.   The method of claim 30, wherein said IFN-β is glycosylated or unglycosylated.

34.   The method of claim 30, wherein said IFN-β is recombinantly produced.

25   35.   The method of claim 30, wherein said IFN-β has at least 80% amino acid sequence identity with the amino acid sequence set forth in SEQ ID NO:1 as calculated using the ALIGN program with a PAM 120 weight residue table, a gap length penalty of 12, and a gap penalty of 4.

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